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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,276	03/07/2001	John W. Erickson	207596	9981

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EXAMINER

LE, EMILY M

ART UNIT: PAPER NUMBER

1648

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,276

Applicant(s)

ERICKSON ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004 and 01 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/01/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/22/04 has been entered.

Decision on Petition

2. Applicant's request for correction of inventorship under 37 C.F.R. § 1.48(a) is acknowledged. Applicant requests the inventorship to be amended to include:

Name: Arun Ghosh

City and State: River Forest, Illinois

Country of citizenship: United States.

Petition is **DENIED** for the following reason(s): Applicant's submission is not in compliance with 37 C.F.R. § 1.48, which requires an oath or declaration by each actual inventor or inventors listing the entire inventive entity to be submitted. In the instant, none of the submitted oath(s) is by each actual inventor listing the entire inventive entity. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Status of Claims

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3. Claims 1-62 are cancelled. Claims 63-77 are added, pending, and under examination. It is noted that newly submitted claims are directed to a patentably distinct invention than previously examined invention.

Applicants are reminded that pursuant to M.P.E.P. § 818.02(a) where claims to another invention are properly added and entered in the application before an action is given, they are treated as original claims for purposes of restriction only. The claims originally presented and acted upon by the Office on their merits determine the invention elected by an applicant in the application, and in any request for continued examination (RCE) which has been filed for the application. Subsequently presented claims to an invention other than that acted upon should be treated as provided in M.P.E.P. § 821.03. Accordingly, newly submitted claims are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention currently claimed is directed at a genus of compounds; whereas, the invention previously presented is directed to a method of using the compounds. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. (refer to 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03).

Applicants are reminded that the presentation of claims for a different invention after an office action is governed by 37 C.F.R. § 1.145 which states: "If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required

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to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in § 1.143 and 1.144.”

In the instant, in view advancing prosecution and RCE filing, newly submitted invention is examined within.

Information Disclosure Statement

4. The information disclosure statement filed 03/02/2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because non-US patent documents are listed in the U.S. Patent Documents section of the form. Applicant is reminded that the cited section is for U.S. Patents and U.S. PreGrant Publications. Items currently listed in this section will not be considered. Should Applicant need to list pending applications that have not been published, Applicant is required to list the application in the non-patent literature section of the form. Furthermore, Applicant should only list the application only once. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 68-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68-76 recites the limitation "Ar" in formula IC, ID, and line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. "Ar" is not previously identified as a substituent for R⁶.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 63-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Vazquez et al. (WO 95/06030, published March 02, 1995).

The claims are directed to a chemical compound having the structure of formula I, particularly the compound defined in claim 76, along with a pharmaceutical composition comprising the compound.

Vazquez et al. teaches of chemical compounds having the same structural requirement set forth in formula I. Additionally, Vazquez et al. also teaches a compound that is the same as that identified in claim 76, and pharmaceutical compositions comprising the compounds. [Entire reference, particularly pages 202 and 204.] In the instant Vazquez et al. teaches the same compounds as that instantly claimed. Ergo, Vazquez et al. anticipates the claimed invention.

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It is noted that the claims requires the claimed compositions inhibit multi-drug resistant retroviral protease. In the instant, Vazquez et al. teaches the compositions are effective as retroviral protease inhibitors. Vazquez et al. is silent on the ability of the compositions to inhibit multi-drug resistant retroviral protease. However, MPEP § 212, which states, "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In the instant, it appears that Applicant discovered that the composition of Vazquez et al. was capable of inhibiting multi-drug resistant retroviral proteases; however, the discovery does not render the known composition patentably new to Applicant.

Double Patenting

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10. Claims 63-77 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 63-77 of copending Application No. 11/030632. The claims are exact duplicate of one another. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 63-67 and 77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6649651. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims is generic to all that is recited in claims 1-6 of U.S. Patent No. 6649651. That is, claims 1-6 of U.S. Patent No. 6649651 fall entirely within the scope of the examined claims or, in other words, the examined claims is anticipated by claims 1-6 of U.S. Patent No. 6649651. Specifically, the first compound of claim 1 of the patent is the compound of claim 63 when: X is O, Q is C(O), R² is H, m is 1, R³ is a aryl, R⁴ is OH, R⁵ is a C4 alkyl, W is SO₂, R₆ is, R¹ is H, Y is O, Z is O, n is 2.

13. Claims 63-77 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 and 10-21 of copending Application No.

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10/382435, U.S PreGrant Pub No. 20040039016. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims is generic to all that is recited in claims 11-7 and 10-21 of copending Application No. 10/382435, U.S PreGrant Pub No. 20040039016. That is, claims 1-7 and 10-21 of copending Application No. 10/382435, U.S PreGrant Pub No. 20040039016 fall entirely within the scope of the examined claims or, in other words, the examined claims is anticipated by claims 1-7 and 10-21 of copending Application No. 10/382435, U.S PreGrant Pub No. 20040039016. Specifically, the first compound of claim 1 of the patent application is the compound of claim 63 when: A is R¹; X is O, Q is C(O); R² is H; m is 1; R³ is a aryl (-C₆H₅); R⁴ is H; R⁵ is an C₁-C₆ alkyl or C₁-C₆ alkenyl; W and R⁶ is R³.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The instant rejection is made on the basis that Arun Ghosh as a co-inventor, as indicated in Applicant's 03/01/05 submission.

14. Claims 63-67 and 77 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2, 6-8 and 16-21 of copending Application No.

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10/337349, U.S PreGrant Pub No: 20030171423. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims is generic to all that is recited in claims 1-2, 6-8 and 16-21 of copending Application No. 10/337349, U.S PreGrant Pub No: 20030171423. That is, claims 1-2, 6-8 and 16-21 of copending Application No. 10/337349, U.S PreGrant Pub No: 20030171423 fall entirely within the scope of the examined claims or, in other words, the examined claims is anticipated by claims 1-2, 6-8 and 16-21 of copending Application No. 10/337349, U.S PreGrant Pub No: 20030171423. Specifically, the first compound of claim 1 of the patent application is the compound of claim 63 when: A is X; X, Q, R² and partial structure of formula (I) are A; R³, m, R⁴ and partial structure of formula (I) are B; R⁵, W and partial structure of formula (I) are A'; R⁶ is X'

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

15. Claims 63-67 and 77 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28,

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30-34 and 36-40 of copending Application No. 10/337699, U.S PreGrant Pub No: 20040009890 in view of the disclosure of U.S. PreGrant Pub. No. 20040039016. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed Cir. 1985).

While it is noted that claims 28, 30-34 and 36-40 of copending Application No. 10/337699, U.S PreGrant Pub No: 20040009890 do not recite specific chemical structures; however, it is deduced that the composition claimed in claims 28, 30-34 and 36-40 of copending Application No. 10/337699, U.S PreGrant Pub No: 20040009890 is encompassed by the composition of the examined claims, in view of '016 disclosure. '016 discloses that Compound I of '890 have an IC50, variant/IC50, wild type ratio of Compound I of '890 have IC50 value of .8. (See composition no. 130, page 34 of '016 disclosure).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims is generic to all that is recited in claims 28, 30-34 and 36-40 of copending Application No. 10/337699, U.S PreGrant Pub No: 20040009890. That is, claims 28, 30-34 and 36-40 of copending Application No. 10/337699, U.S PreGrant Pub No: 20040009890 fall entirely within the scope of the examined claims or, in other words, the examined claims is anticipated by claims 28,

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30-34 and 36-40 of copending Application No. 10/337699, U.S. PreGrant Pub No: 20040009890. Specifically, the compound of claim 28 of the patent application is the compound of claim 63 when: Y and Z are O; X is O; Q is C(O); R² is H; m is 1; R³ is a aryl (-C₆H₅); R⁴ is H; R⁵ is an C₁-C₄ alkyl; W is SO₂; and R⁶ is aryl, wherein one of the hydrogen is substituted with a OCH₃.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. No claim is allowed.

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Nos. 6060476, 5843946, 5744481, 5691372, 5585397; WO 9967254, WO 9633187, WO 9506030, WO 9405639, and WO 9404492. All of the above references teach protease inhibitors that resemble the compounds instantly claimed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey S. Parkin, Ph.D.
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Art Unit 1648



Emily Le
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